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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/584,730

06/23/2006

Tsuneo Yasuma

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EXAMINER

COPPINS, JANET L

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/584,730	Applicant(s) YASUMA ET AL.	
	Examiner JANET L. COPPINS	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-11 and 18 is/are allowed.
- 6) ☒ Claim(s) 13, 14 and 17 is/are rejected.
- 7) ☒ Claim(s) 12 and 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/23/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-14, 17 and 18 are currently pending in the instant application.

Priority

2. The instant application is a 371 of International Application No. PCT/JP2004/O19749 filed December 24, 2004.

Information Disclosure Statement

3. Applicants' Informational Disclosure Statement (IDS), submitted June 23, 2006, has been considered by the Examiner. Please refer to the signed copy of Applicants' PTO-1449 form, submitted herewith.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Regarding claim 17, the claim is rejected under 35 U.S.C. 112, first paragraph, as being a reach-through claim. The claim is directed to a method of modulating a receptor, yet the claim does not meet the requirements for "how to use" under 35 U.S.C. 112, first paragraph, as stated above. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility, or a well established utility for the reasons set forth below, one skilled in the art clearly would not know how to use the claimed invention. The claim is directed to a method of "modulating GPR40 receptor function," yet the claim fails to present a tangible use, since Applicants have failed to recite a closed set of specific disorders or conditions to be treated, that are encompassed by the claim.

Applicants are claiming methods of treating an extremely broad number of diseases or conditions, encompassed by the language of claim 17. Applicants have provided evidence that the compounds are effective for inhibiting GPR40 receptor binding within certain cell lines, however “the selection of the examples...used as the disclosure to support a claim must be adequately representative of the area covered by it,” please see *In re Cavallito et al.* (CCPA 1970) 429 F2d 452, 166 USPQ 552. Therefore the instant specification is lacking significant data to accommodate as many diseases or conditions as the claims are alleging by broadly reciting, “A method of treating a disorder mediated by an androgen receptor...”

The argument that the diseases claimed by the Applicants are all treated by modulating the GPR40 receptor is insufficient support that the claimed compounds have specific efficacy in current available form for treating all of the diseases and conditions encompassed by the language of claim 17. One of ordinary skill in the art, without direction, would be unable to treat each and every disease/condition encompassed by claim 17 using the instant claimed compounds. One would need to determine which disorders or conditions would be benefited by “modulating,” i.e. either agonizing or antagonizing the GPR40 receptor, and would furthermore then have to determine whether the claimed compounds would provide treatment of all of the diseases and conditions by said activity.

Thus, the specification fails to provide sufficient support of the broad use of the compound of the claim 1 for the treatment of all diseases/conditions encompassed by the language of claim 17. As a result, necessitating one of skill to perform an exhaustive search for which claimed diseases can be treated by the compound of claim 1 in order to practice the claimed method. The Examiner suggests claiming the possible diseases and conditions that are

Art Unit: 1626

enabled by the Specification and can be treated by administering the compound of the instant claims, rather than claiming the mechanism, which is speculative. For example, the Examiner recommends the following claim language, "A method for modulating GPR40 receptor function in a mammal, for treating type II diabetes, obesity, insulin resistance or impaired glucose tolerance."

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 13 and 14 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13 and 14 are both directed to a "pharmaceutical agent," however it is unclear what is meant by the term "agent" from the claims themselves. The recited terminology is vague and indefinite, and it is difficult to ascertain whether Applicants are intending to claim a compound or a composition. The Examiner recommends replacing every occurrence of the term "agent" with "composition."

Claim Objections

8. Claims 12 and 14 are objected to as being duplicates of claim 13. Claim 12 is directed to a "GPR40 receptor function modulator," which merely describes a function or contemplated use of a compound of claim 1. In claim 14, the claim is directed to a "pharmaceutical agent" for the "prophylaxis or treatment of diabetes," which is a future intended use of the compound of claim 13. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the

Art Unit: 1626

invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction.

Therefore, claims 12 and 14, as presently worded, are duplicates of claim 13.

Conclusion

9. In conclusion, claims 1-14, 17 and 18 are currently pending in the application. Claims 1-11 and 18 appear allowable over the prior art, claims 13, 14 and 17 are rejected, and claims 12 and 14 are objected to.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JANET L. COPPINS whose telephone number is (571)272-0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Janet L. Coppins
June 23, 2008

/Kamal A. Saeed/
Primary Examiner, Art Unit 1626

Application/Control Number: 10/584,730
Art Unit: 1626

Page 6